WELSH STATUTORY INSTRUMENTS

2013 No. 898

The National Health Service (Pharmaceutical Services) (Wales) Regulations 2013

PART 1

Introduction

Title, commencement and application

1.—(1) The title of these Regulations is the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013.

(2) These Regulations come into force on 10 May 2013.

(3) These Regulations apply in relation to Wales.

Interpretation

2.—(1) In these Regulations—

"the 1992 Regulations" ("*Rheoliadau 1992*") means the National Health Service (Pharmaceutical Services) Regulations 1992(**1**), in force immediately before these Regulations come into force;

"the 2005 Regulations" ("*Rheoliadau 2005*") means the National Health Service (Pharmaceutical Services) Regulations 2005(**2**) as in force immediately before 1 September 2012;

"the 2006 Act" ("*Deddf 2006*") means the National Health Service (Wales) Act 2006;

"advanced electronic signature" ("*llofnod electronig uwch*") means an electronic signature which is—

(a) uniquely linked to the signatory;

(b) capable of identifying the signatory;

(c) created using means that the signatory can maintain under his or her sole control; and

(d) linked to the data to which it relates in such a manner that any subsequent change of data is detectable;

"APMS" ("*GMDdA*") means primary medical services provided in accordance with an APMS contract;

"APMS contract" ("*contract GMDdA*") means an arrangement to provide primary medical services made with a Local Health Board under section 41(2)(b) of the 2006 Act (primary medical services);

(**1**) S.I.1992/662. Relevant amending instruments are S.I.2007/205 (W.19), S.I. 2009/1491 (W.144), S.I. 2010/868 (W.90), S.I. 2010/1648 (W.156) and S.I. 2011/2907 (W.311).
(**2**) S.I. 2005/641. Revoked by S.I. 2012/1909.

"APMS contractor" ("*contractwr GMDdA*") means a party to an APMS contract, other than a Local Health Board;

"appliance" ("*cyfarpar*") means an appliance which is included in a list approved by the Welsh Ministers for the purposes of section 80 of the 2006 Act (arrangements for pharmaceutical services);

"appliance use review service" ("*gwasanaeth adolygu defnyddio cyfarpar*") means arrangements made in accordance with directions under section 81 of the 2006 Act (arrangements for additional pharmaceutical services) for an NHS pharmacist or NHS appliance contractor to review a person's use of any specified appliance;

"appropriate non-proprietary name" ("*enw amherchnogol priodol*") means a non-proprietary name which is not mentioned in Schedule 1 to the Prescription of Drugs Regulations or, except where the conditions in paragraph 42(2) of Schedule 6 to the GMS Regulations are satisfied, in Schedule 2 to the Prescription of Drugs Regulations;

"associated batch issue" ("*swp-ddyroddiad cysylltiedig*") means, in relation to a non-electronic repeatable prescription, one of the batch issues relating to that prescription and containing the same date as that prescription;

"bank holiday" ("*gŵ yl banc*") means any day that is specified or proclaimed as a bank holiday in Wales pursuant to section 1 of the Banking and Financial Dealings Act 1971(**3**);

"batch issue" ("*swp-ddyroddiad*") means a form provided by a Local Health Board and issued by a repeatable prescriber at the same time as a non-electronic repeatable prescription to enable a NHS pharmacist or NHS appliance contractor to receive payment for the provision of repeat dispensing services which is in the required format, and which—

(a) is generated by a computer and not signed by a repeatable prescriber;

(b) relates to a particular non-electronic repeatable prescription and contains the same date as that prescription;

(c) is issued as one of a sequence of forms, the number of which is equal to the number of occasions on which the drugs or appliances ordered on the non-electronic repeatable prescription may be provided; and

(d) specifies a number denoting its place in the sequence referred to in sub-paragraph (c);

"Charges Regulations" ("*Rheoliadau Ffioedd*") means the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007(**4**);

"child" ("*plentyn*") means a person who has not attained the age of 16 years;

"Community Health Council" ("*Cyngor Iechyd Cymuned*") means a Community Health Council retained or established under section 182 of the 2006 Act (community health councils);

"conditional inclusion" ("*cynnwys yn amodol*") means inclusion in a pharmaceutical list or the grant of preliminary consent to be included in a pharmaceutical list subject to conditions imposed under Part 6 of these Regulations and "conditionally include" ("cynnwys yn amodol") is to be construed accordingly;

"contingent removal" ("*tynnu digwyddiadol*") means removal from a pharmaceutical list contingently, within the meaning of section 108 of the 2006 Act (contingent removal), and "contingently remove" ("*tynnu yn ddigwyddiadol*") is to be construed accordingly;

"controlled locality" ("*ardal reoledig*") means an area which a Local Health Board has determined to be rural in accordance with regulation 6 (areas that are controlled localities), which the Welsh Ministers have determined on appeal, in accordance with Parts 1 and 2

(**3**) 1971 c. 80.
(**4**) S.I. 2007/121 (W.11) amended by S.I. 2007/1112 (W.117), S.I. 2009/1175 (W.102), S.I. 2009/2607 (W.210), S.I. 2010/231 and S.I. 2010/1647 (W.155).

of Schedule 3, to be rural or which is a controlled locality by virtue of the operation of regulation 6(1);

"dentist" ("*deintydd*") means a dental practitioner;

"directed services" ("*gwasanaethau cyfeiriedig*") means additional pharmaceutical services provided in accordance with directions under section 81 of the 2006 Act (arrangements for additional pharmaceutical services);

"director" ("*cyfarwyddwr*") means—

(a) a director of a body corporate; or

(b) a member of the body of persons controlling a body corporate (whether or not a limited liability partnership);

"dispensing doctor" ("*meddyg fferyllol*") means a doctor who provides pharmaceutical services under arrangements with a Local Health Board made under regulation 20 (arrangements for the provision of pharmaceutical services by doctors);

"dispensing doctor list" ("*rhestr meddygon fferyllol*") means a list that a Local Health Board is required to prepare and maintain under regulation 4 (preparation and maintenance of dispensing doctor lists);

"doctor" ("*meddyg*") means a registered medical practitioner;

"drugs" ("*cyffuriau*") includes medicines;

"Drug Tariff" ("*Tariff Cyffuriau*") has the meaning given to it in regulation 41 (the Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors);

"electronic communication" ("*cyfathrebiad electronig*") has the meaning given in section 15(1) of the Electronic Communications Act 2000(**5**) (general interpretation);

"electronic prescription" ("*presgripsiwn electronig*") means an electronic prescription form or an electronic repeatable prescription;

"electronic prescription form" ("*ffurflen bresgripsiwn electronig*") means data created in an electronic form for the purpose of ordering a drug or appliance which—

(a) is signed with a prescriber's advanced electronic signature;

(b) is transmitted as an electronic communication to a nominated NHS pharmacist, NHS appliance contractor or dispensing doctor by the ETP service; and

(c) does not indicate that the drug or appliance ordered may be provided more than once;

"electronic repeatable prescription" ("*presgripsiwn amlroddadwy electronig*") means data created in an electronic form which—

(a) is signed with a repeatable prescriber's advanced electronic signature;

(b) is transmitted as an electronic communication to a nominated NHS pharmacist, NHS appliance contractor or dispensing doctor by the ETP service;

(c) indicates that the drugs or appliances ordered may be provided more than once; and

(d) specifies the number of occasions on which they may be provided;

"electronic signature" ("*llofnod electronig*") has the same meaning as in section 7 of the Electronic Communications Act 2000 (electronic signatures and related certificates);

"employment" ("*cyflogaeth*") includes unpaid employment and employment under a contract for services and "employed" ("*cyflogedig*"), "employer" ("*cyflogwr*") and "employs" ("*cyflogi*") are to be construed accordingly;

(**5**) 2000 c. 7. The definition of "electronic communication" was amended by the Communications Act 2003 (c. 21), Schedule 17 paragraph 158.

"equivalent body" ("*corff cyfatebol*") means the National Health Service Commissioning Board in England, a Health Board in Scotland, a Health and Social Services Board in Northern Ireland or any successor body in England, Scotland or Northern Ireland and, in relation to any time prior to 1 April 2003, a Health Authority in Wales or in relation to any time prior to 1 April 2013 and after 30 September 2002 a Primary Care Trust in England, or in relation to any time prior to 1 October 2002 a Health Authority in England;

"equivalent list" ("*rhestr gyfatebol*") means a list kept by an equivalent body;

"essential services" ("*gwasanaethau hanfodol*") for NHS pharmacists means the services specified in paragraph 3 of Schedule 4 and for NHS appliance contractors means the services specified in paragraphs 3 to 11 of Schedule 5;

"EEA" ("*AEE*") means the European Economic Area created by the EEA Agreement;

"ETP service" ("*gwasanaeth TPE*") means the 2-dimensional barcoded prescription service which forms part of the information technology systems in prescribing and dispensing systems in Wales and used by the health service in Wales to transfer and hold prescription information relating to patients;

"General Pharmaceutical Council Register" ("*Cofrestr y Cyngor Fferyllol Cyffredinol*") means the register maintained under article 19 of the Pharmacy Order 2010(**6**) (Establishment, maintenance of and access to the Register);

"GMS contract" ("*contract GMC*") means a general medical services contract under section 42 of the 2006 Act (general medical services contracts: introductory);

"GMS contractor" ("*contractwr GMC*") means a party to a GMS contract, other than the Local Health Board;

"GMS Regulations" ("*Rheoliadau GMC*") means the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004(**7**);

"health care professional" ("*gweithiwr proffesiynol gofal iechyd*") means a person other than a social worker who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Healthcare Professions Act 2002(**8**);

"independent nurse prescriber" ("*nyrs sy'n rhagnodi'n annibynnol*") means a person—

(a) who is registered in the Nursing and Midwifery Register; and

(b) against whose name in that register is recorded an annotation signifying that he or she is qualified to order drugs and appliances as a community practitioner nurse prescriber, a nurse independent prescriber or a nurse independent/supplementary prescriber;

"joint discipline committee" ("*cyd-bwyllgor disgyblu*") has the same meaning as in regulation 2 of the National Health Service (Service Committees and Tribunal) Regulations 1992(**9**) (interpretation);

"LHBMS" ("*GMBILl*") means primary medical services provided by a Local Health Board under section 41(2)(a) of the 2006 Act (primary medical services);

"LHBMS practice" ("*practis GMBILl*") means a practice providing LHBMS;

"licensing or regulatory body" ("*corff trwyddedu neu reoleiddio*") means any body that licenses or regulates any profession of which the person is or has been a member, and includes any body which licenses or regulates any such profession in a country other than the United Kingdom;

(**6**) S.I. 2010/231.
(**7**) S.I. 2004/478 (W.48). Amending instruments include S.I. 2004/1017 (W.114), S.I. 2006/358 (W.46), S.I. 2006/945 (W.94), S.I. 2007/121 (W.11), S.I. 2007/205 (W.19), S.I. 2008/1329 (W.138), S.I .2008/1425 (W.147), S.I. 2010/729 (W.70), S.I. 2010/1647 (W.155) and S.I. 2011/704 (W.108).
(**8**) 2002 c. 17. Section 25 has been amended by the Health and Social Care Act 2008 (c. 14).
(**9**) S.I. 1992/664. The definition of "joint discipline committee" was inserted by S.I. 1996/703.

"list" ("*rhestr*"), unless the context otherwise requires, means a pharmaceutical list or a dispensing doctor list;

"listed premises" ("*mangre restredig*") means the premises that are included in—

(a) a pharmaceutical list; or

(b) a dispensing doctor list pursuant to regulation 4 (preparation and maintenance of dispensing doctor lists);

"Local Health Board" ("*Bwrdd Iechyd Lleol*") means a Local Health Board established under section 11 of the 2006 Act (local health boards);

"Local Medical Committee" ("*Pwyllgor Meddygol Lleol*") means a committee recognised under section 54 of the 2006 Act (local medical committees);

"Local Pharmaceutical Committee" ("*Pwyllgor Fferyllol Lleol*") means a committee recognised under section 90 of the 2006 Act (local pharmaceutical committees);

"local pharmaceutical services" ("*gwasanaethau fferyllol lleol*") means services of a kind which may be provided under section 80, or by virtue of section 81 of the 2006 Act, other than practitioner dispensing services, and which are provided under a pilot scheme;

"medical performers list" ("*rhestr cyflawnwyr meddygol*") means a list of doctors prepared and published pursuant to regulation 3(1) of the National Health Service (Performers Lists) (Wales) Regulations 2004(**10**);

"national disqualification" ("*anghymhwysiad cenedlaethol*") means—

(a) a national disqualification as mentioned in section 115 (2) and (3) of the 2006 Act (national disqualification);

(b) a national disqualification as mentioned in section 159 (2) and (3) of the National Health Service Act 2006(**11**) (national disqualification);

(c) any decision in Scotland or Northern Ireland corresponding to a national disqualification under section 115 (2) and (3) of the 2006 Act; and

(d) any other decision that was a national disqualification for the purposes of the 2005 Regulations;

"NHS appliance contractor" ("*contractwr cyfarpar GIG*") means a person who is included in a pharmaceutical list under regulation 3 (preparation and maintenance of pharmaceutical lists) for the provision of pharmaceutical services only by the provision of appliances;

"NHS Business Services Authority" ("*Awdurdod Gwasanaethau Busnes y GIG*") means the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005(**12**)

"NHS pharmacist" ("*fferyllydd GIG*") means—

(a) a registered pharmacist; or

(b) a person lawfully carrying on a retail pharmacy business in accordance with section 69 of the Medicines Act 1968(**13**),

whose name is included in a pharmaceutical list under regulation 3 (preparation and maintenance of pharmaceutical lists) for the provision of pharmaceutical services in particular by the provision of drugs;

(**10**) S.I. 2004/1020 (W.117).
(**11**) 2006 c. 41. Section 159 has been amended by S.I. 2010/22.
(**12**) S.I. 2005/2414 as amended by S.I. 2006/632.
(**13**) 1968 c. 67.

"NHS services" ("*gwasanaethau GIG*") means services provided as part of the health service in Wales;

"non-electronic prescription form" ("*ffurflen bresgripsiwn anelectronig*") means a prescription form which falls within sub-paragraph (a) of the definition of "prescription form";

"non-electronic repeatable prescription" ("*presgripsiwn amlroddadwy anelectronig*") means a prescription which falls within sub-paragraph (a)(i) of the definition of "repeatable prescription";

"non-proprietary name" ("*enw amherchnogol*") means a name which is, or which is a permitted variation of—

(a) an International Nonproprietary Name (INN);

(b) an International Nonproprietary Name Modified (INNM);

(c) a British Approved Name (BAN);

(d) a British Approved Name Modified (BANM); or

(e) an approved name,

and for this purpose these names (and their permitted variations) have the same meanings as in a list of names which has been prepared and caused to be published by the British Pharmacopoeia Commission and which has not been superseded(**14**);

"notice" ("*hysbysiad*") means a notice in writing and "notify" ("*hysbysu*") is to be construed accordingly;

"nurse independent prescriber" ("*nyrs-ragnodydd annibynnol*") means a person—

(a) whose name is registered in the Nursing and Midwifery Register;

(b) against whose name in that register is recorded an annotation or entry signifying that he or she is qualified to order drugs, medicines and appliances as:

(i) a nurse independent prescriber, or

(ii) a nurse independent/supplementary prescriber, and

(c) who, in respect of a person practising in Wales on or after 19 July 2010, has passed an accredited course to practise as a nurse independent prescriber;

"Nursing and Midwifery Register" ("*Cofrestr Nyrsio a Bydwreigiaeth*") means the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001(**15**) (establishment and maintenance of register);

"optometrist independent prescriber" ("*optometrydd-ragnodydd annibynnol*") means a person—

(a) who is an optometrist registered in the register of optometrists maintained under section 7 of the Opticians Act 1989(**16**) (which relates to the register of optometrists and the register of dispensing opticians) or the register of visiting optometrists from relevant European States maintained under section 8B(1)(a) of that Act; and

(b) against whose name is recorded an annotation signifying that the optometrist is qualified to order drugs, medicines and appliances as an optometrist independent prescriber;

"originating events" ("*digwyddiadau cychwynnol*") means the events that gave rise to the conviction, investigation, proceedings, suspension, refusal to admit, conditional inclusion, removal or contingent removal that took place;

(**14**) The British Pharmacopoeia 2013 is the leading collection of standards for UK medicinal products and pharmaceutical substances and is available at www.pharmacopoeia.co.uk.
(**15**) S.I. 2002/253; as amended by S.I. 2009/1182.
(**16**) 1989 c. 44; amended by S.I. 2005/848.

"outline consent" ("*cydsyniad amlinellol*") has the meaning given to it in regulation 24(1)(a) (outline consent and premises approval);

"outstanding pharmacy application" ("*cais am fferyllfa yn yr arfaeth*") has the meaning given to it in regulation 25(11) (taking effect of outline consent and premises approval);

"patient list" ("*rhestr cleifion*") means a list of patients kept in accordance with paragraph 14 (list of patients) of Schedule 6 to the GMS Regulations or in respect of an APMS contractor or an LHBMS practice, in accordance with directions given by the Welsh Ministers under section 12(3) of the 2006 Act;

"pharmaceutical discipline committee" ("*pwyllgor disgyblu fferyllol*") has the same meaning as in regulation 2 of the National Health Service (Service Committees and Tribunal) Regulations 1992(**17**);

"pharmaceutical list" ("*rhestr fferyllol*") means a list that a Local Health Board is required to prepare and maintain under regulation 3 (preparation and maintenance of pharmaceutical lists);

"pharmaceutical services" ("*gwasanaethau fferyllol*") means pharmaceutical services that fall within section 80 of the 2006 Act (arrangements for pharmaceutical services) and do not include directed services;

"pharmacist independent prescriber" ("*fferyllydd-ragnodydd annibynnol*") means a registered pharmacist against whose name in Part 1 of the General Pharmaceutical Council Register or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(**18**) (which relates to registers and the registrar) is recorded an annotation signifying that he or she is qualified to order drugs, medicines and appliances as a pharmacist independent prescriber;

"pharmacy" ("*fferyllfa*") means—

(a) listed premises under regulation 3 (preparation and maintenance of pharmaceutical lists) at which pharmaceutical services are provided by an NHS pharmacist pursuant to arrangements made under section 80 of the 2006 Act; or

(b) premises where under a pharmacy pilot scheme under section 92 of the 2006 Act (Pilot schemes) the range of pharmaceutical services and the hours on which they are provided are comparable to a pharmacy falling within sub-paragraph (a);

"pilot scheme" ("*cynllun peilot*") has the same meaning as in the term "pilot scheme" in section 92(2) of the 2006 Act (Pilot schemes);

"practice premises" ("*mangre practis*"), in relation to a provider of primary medical services, means the address or addresses specified in the contract (in the case of a GMS or APMS contractor) or practice statement (in the case of an LHBMS practice) at which services are to be provided under the contract or practice statement;

"preliminary consent" ("*cydsyniad rhagarweiniol*") has the meaning given to it in regulation 12 (applications for preliminary consent and effect of preliminary consent);

"premises approval" ("*cymeradwyaeth mangre*") has the meaning given to it in regulation 24(1)(b) (outline consent and premises approval) and includes temporary premises approval granted under regulation 28(13) (premises approval: additional and new premises after outline consent has taken effect) or residual premises approval granted under regulation 29(9) (premises approval: practice amalgamations);

"prescriber" ("*rhagnodydd*") means a doctor, dentist, pharmacist independent prescriber, independent nurse prescriber, nurse independent prescriber, optometrist independent prescriber or a supplementary prescriber;

(**17**) S.I. 1992/664. The definition of "pharmaceutical discipline committee" was inserted by S.I. 1996/703.
(**18**) S.I. 1976/1213 (N.I. 22).

"prescription form" ("*ffurflen bresgripsiwn*") means—

(a) a form provided by a Local Health Board, an NHS Trust, an NHS Foundation Trust or an equivalent body and issued by a prescriber; or

(b) an electronic prescription form,

that enables a person to obtain pharmaceutical services and does not include a repeatable prescription;

"Prescription of Drugs Regulations" ("*Rheoliadau Rhagnodi Cyffuriau*") means the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Wales) Regulations 2004(**19**);

"provider of primary medical services" ("*darparwr gwasanaethau meddygol sylfaenol*") means a GMS contractor, APMS contractor, or an LHBMS practice;

"registered pharmacist" ("*fferyllydd cofrestredig*") means a person who is registered in Part 1 of the General Pharmaceutical Council Register or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976;

"relevant APMS contractor" ("*contractwr GMDda perthnasol*"), in relation to any doctor, means the APMS contractor, where the doctor is an APMS contractor, or where he or she is not, the APMS contractor by whom the doctor is employed or engaged;

"relevant European State" ("*Gwladwriaeth Ewropeaidd perthnasol*") means an EEA State or Switzerland;

"relevant GMS contractor" ("*contractwr GMC perthnasol*"), in relation to any doctor, means the GMS contractor, where the doctor is a GMS contractor or, where he or she is not, the GMS contractor by whom the doctor is employed or engaged;

"relevant list" ("*rhestr berthnasol*") means—

(a) a pharmaceutical list or an equivalent list; or

(b) a list maintained by a Local Health Board or an equivalent body of approved performers or providers of primary medical, dental or ophthalmic services;

"relevant patient list" ("*rhestr cleifion berthnasol*") means, in relation to a doctor who is (or is a legal and beneficial shareholder in a company which is) a GMS contractor or APMS contractor, the patient list for that contractor or, where the doctor is not a contractor, means the patient list for the GMS contractor or APMS contractor by whom the doctor is employed or engaged or for the LHBMS practice within which the doctor provides primary medical services;

"Remission of Charges Regulations" ("*Rheoliadau Peidio â Chodi Tâl*") means the National Health Service (Travelling Expenses and Remission of Charges) (Wales) Regulations 2007(**20**);

"repeat dispensing services" ("*gwasanaethau amlweinyddu*") means pharmaceutical services which involve the provision of drugs or appliances by an NHS pharmacist or an NHS appliance contractor in accordance with a repeatable prescription;

"repeatable prescriber" ("*rhagnodydd amlroddadwy*") means a person who is—

(a) a GMS contractor who provides repeatable prescribing services under the terms of its contract which give effect to paragraph 40 (repeatable prescribing services) of Schedule 6 to the GMS Regulations;

(b) an APMS contractor who provides repeatable prescribing services under the terms of its agreement which give effect to a provision in directions made by Welsh Ministers

(**19**) S.I. 2004/1022 (W.119) amended by S.I. 2005/366 (W.32), S.I. 2009/1838 (W.166) and S.I. 2009/1977 (W.176).
(**20**) S.I. 2007/1104 (W.116) amended by S.I. 2008/1480 (W.153), S.I. 2008/2568 (W.226), S.I. 2009/54 (W.18), S.I. 2009/709 (W.61), S.I. 2009/1824 (W.165), S.I. 2009/2365 (W.193), S.I. 2010/1237 (W.107), S.I. 2010/2759 (W.231), S.I. 2011/681 (W.100), S.I. 2011/1940 (W.208) and S.I. 2012/800 (W.109).

under section 12(3) of the 2006 Act in relation to APMS contracts which is the equivalent provision to paragraph 40 of Schedule 6 to the GMS Regulations; or

(c) employed or engaged by—

(i) a GMS contractor who provides repeatable prescribing services under the terms of a contract which give effect to paragraph 40 of Schedule 6 to the GMS Regulations,

(ii) an APMS contractor who provides repeatable prescribing services under the terms of an agreement which give effect to a provision in directions made by the Welsh Ministers under section 12(3) of the 2006 Act in relation to APMS contracts which is the equivalent provision to paragraph 40 of Schedule 6 to the GMS Regulations, or

(iii) a Local Health Board for the purposes of providing primary medical services within a LHBMS practice which provides repeatable prescribing in accordance with a provision in directions made by the Welsh Ministers under section 12(3) of the 2006 Act in relation to LHBMS which is the equivalent provision to paragraph 40 of Schedule 6 to the GMS Regulations;

"repeatable prescription" ("*presgripsiwn amlroddadwy*") means a prescription contained in a form provided by a Local Health Board which—

(a) is either—

(i) generated by computer but signed by a repeatable prescriber, or

(ii) a form created in an electronic format, identified using a repeatable prescriber's code and transmitted as an electronic communication to a nominated NHS pharmacist, NHS appliance contractor or dispensing doctor by the ETP service;

(b) is issued or created to enable a person to obtain pharmaceutical services; and

(c) indicates that the drugs or appliances ordered on that form may be provided more than once, and specifies the number of occasions on which they may be provided;

"reserved location" ("*lleoliad neilltuedig*") has the meaning given to it by regulation 11(4) (locations in controlled localities that are reserved locations);

"restricted availability appliance" ("*cyfarpar argaeledd cyfyngedig*") means an appliance which is approved for particular categories of persons or particular purposes only;

"Scheduled drug" ("*cyffur Atodlen*") means a drug or other substance specified in Schedule 1 or 2 to the Prescription of Drugs Regulations (which relate to drugs, medicines and other substances not to be ordered under a general medical services contract or that may be ordered only in certain circumstances);

"specified appliance" ("*cyfarpar penodedig*") means—

(a) any of the following appliances listed in Part IXA of the Drug Tariff—

(i) a catheter appliance (including a catheter accessory and maintenance solution),

(ii) a laryngectomy or tracheostomy appliance,

(iii) an anal irrigation system,

(iv) a vacuum pump or constrictor ring for erectile dysfunction, or

(v) a wound drainage pouch;

(b) an incontinence appliance listed in Part IXB of the Drug Tariff; or

(c) a stoma appliance listed in Part IXC of the Drug Tariff;

"stoma appliance customisation" ("*addasu cyfarpar stoma*") means the customisation of a quantity of more than one stoma appliance, where—

(a) the stoma appliances to be customised are listed in Part IXC of the Drug Tariff;

(b) the customisation involves modification to the same specification of multiple identical parts for use with each appliance; and

(c) that modification is based on the patient's measurements or a record of those measurements and, if applicable, a template;

"superintendent" ("*uwcharolygydd*") has the same meaning as in section 71 of the Medicines Act 1968(**21**) (bodies corporate);

"supplementary prescriber" ("*rhagnodydd atodol*") means—

(a) a registered pharmacist against whose name in Part 1 of the General Pharmaceutical Council Register or in the register maintained under Article 6 and 9 of the Pharmacy (Northern Ireland) Order 1976 is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a supplementary prescriber;

(b) a person whose name is registered in the Nursing and Midwifery Register and against whose name in that Register is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a nurse independent/supplementary prescriber;

(c) a person—

(i) who is registered in a part of the register maintained under article 5 of the Health and Social Work Professions Order 2001(**22**) (establishment and maintenance of register) which relates to chiropodists and podiatrists, physiotherapists or radiographers, and

(ii) against whose name in that register is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a supplementary prescriber; or

(d) an optometrist against whose name in the register of optometrists maintained under section 7 or 8B(1)(a) of the Opticians Act 1989 is recorded an annotation signifying that the optometrist is qualified to order drugs, medicines and appliances as a supplementary prescriber; and

"Tribunal" ("*Tribiwnlys*") means the First-tier Tribunal established under the Tribunals, Courts and Enforcement Act 2007(**23**).

(2) Where reference is made in these Regulations to a decision of a Local Health Board and that decision is changed on appeal, unless the context otherwise requires, the reference to that decision is to be construed as a reference to the decision changed on appeal.

(3) In these Regulations—

(a) the term "pharmaceutical services" ("*gwasanaethau fferyllol*") in relation to a doctor means those services referred to in regulation 20; and

(b) the term "dispensing services" ("*gwasanaethau gweinyddu*"), in relation to a doctor or GMS contractor means any corresponding service provided, not as pharmaceutical services, but under the terms of a GMS contract which give effect to paragraphs 47 to 51 of Schedule 6 to the GMS Regulations.

(4) Except where expressly provided to the contrary, any document which is required or authorised to be given or sent to a person or body under these Regulations may be given or sent by delivering it to the person or, in the case of a body, to the secretary or general manager of that body, or by sending it in a pre-paid letter addressed to that person or, in the case of a body, to the secretary

(**21**) Section 71 was substituted by section 28 of the Health Act 2006 (c. 28).
(**22**) S.I. 2002/254. Article 5 has been amended by S.I. 2009/1182. The Order was renamed by section 213(4) and (6) of the Health and Social Care Act 2012 (c. 7).
(**23**) 2007 c. 15.

or general manager of that body at his usual or last known address, and delivering it includes sending it electronically to an electronic address which that person has notified for the purpose.

(5) Where the term "community practitioner nurse prescriber" appears in the Human Medicines Regulations 2012(**24**) or the Nursing and Midwifery Register it is to be construed for the purposes of these Regulations as a reference to an "independent nurse prescriber".

(**24**) S.I. 2012/1916.